

REMARKS

The Amendments made herewith are believed to overcome the remaining rejections and objections set forth in the Final Office Action dated January 24, 2007. A Request for Continued Examination (RCE) is being filed concurrently herewith. The Applicants hereby request a telephonic or in-person interview with Examiner Ewoldt, subsequent to the filing of this Amendment and RCE.

Claims 24-25 and 29-32 stand rejected under 35 U.S.C. Section 112, first paragraph, for purported failure to comply with the written description requirement. The amendments to claims 24 and 30 are believed to overcome this rejection. In particular, the omission of the claim language "or the corresponding sequence of another mycobacterial species" and the addition of the recitation, "representing the sequence of the stress protein hsp65 of *Mycobacterium tuberculosis*" (both in claim 24) are believed to overcome the stated rejection. It is now stated with greater particularity which peptide(s) are meant for use in the claimed method of treating Th1-mediated diseases.

Claims 24-26 and 28-32 stand rejected for purported lack of enablement. The Examiner acknowledges that the patent specification is enabling for nasal or oral administration of hsp65 peptides to treat Th-1 mediated diseases. Accordingly, Applicants have herewith added the recitation "wherein the disease is Th-1 mediated" to claim 24. The exemplary diseases previously listed in claim 24, all of which are Th-1 mediated, have been removed from the claim not because Applicants disavow their treatment in any way, but because they are now superfluous in view of the Th-1 mediation language. The Examiner will herewith appreciate that the present specification identifies enablement for more than the nasal and oral routes of administration, for example at specification pages 7 and 11, which illustrate *in vivo* data showing immunization by injection (heel pad) was effective to create the disclosed and claimed effect in rats. Any question of relative effectiveness of routes of administration as between nasal and parenteral is resolved, then, by the injection (parenteral) disclosure at pages 7 and 11 of the specification. It follows then that Applicants ought not to limit their claims to the oral or nasal route(s) of administration. As far as what is being administered by the available routes of administration, claim 24 now defines more clearly what the mycobacterial peptide is that is being administered. The addition of the language "wherein the disease is Th-1 mediated" is believed to resolve any issue with respect to any question raised by Janeway et al., of record. For the record and notwithstanding any other

interpretation of Applicants' earlier statements, the presumed unpredictability of hsp70 administration (Wendling et al. of record) is inconclusive as to the effectiveness of the claimed peptides—in fact the hsp70 peptides are simply different from the hsp65 peptides and this distinction is now more apparent in claim 24.

Finally, claims 24-26 and 28-32 stand rejected under 35 U.S.C. Section 112, first paragraph, for asserted lack of enablement/lack of support in the specification. The amendments to claim 24 in particular are also believed to resolve the Examiner's concern that the claimed invention might not have adequate support in the specification, now that all the claims recite a peptide specifically identified as a particular mycobacterial peptide (from *Mycobacterium tuberculosis*) and not to any other corresponding sequence of another mycobacterial species.

The spelling of aminoacids in claim 24 has been corrected to amino acids.

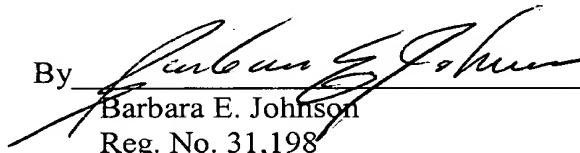
As stated above, the Applicants hereby request a telephonic or in-person interview with Examiner Ewoldt, now that the application is no longer after-Final. A telephone call to the undersigned at 412-471-8815 to facilitate the scheduling of the interview would be greatly appreciated.

Entry of the accompanying Amendment and allowance of pending claims 24-26 and 28-32 are respectfully requested.

Respectfully submitted,

THE WEBB LAW FIRM

By



Barbara E. Johnson

Reg. No. 31,198

Attorney for Applicants

700 Koppers Building

436 Seventh Avenue

Pittsburgh, PA 15219

Telephone: 412-471-8815

Facsimile: 412-471-4094

E-mail: webblaw@webblaw.com